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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,145	11/08/2001	David Leroy Carlton	PU3657USW	8459

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EXAMINER

GAKH, YELENA G

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/009,145	Applicant(s) CARLTON ET AL.	
	Examiner Yelena G. Gakh, Ph.D.	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 and 37-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/08/01</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Election of claims 19-36 without traverse, filed on 08/03/04 is acknowledged. Claims 19-36 are considered on merits. Claims 1-18 and 37-64 are withdrawn from consideration.

Drawings

2. Figure 2 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.121(d)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Information Disclosure Statement

3. The information disclosure statement filed 11/08/01 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. The prior art disclosed by the Applicants in the specification and represented on Figures 1 and 2 is not reflected on IDS form and is not accompanied by a reference.

Specification

4. The abstract of the disclosure is objected to because it is too long. The proper abstract should contain fifteen lines. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 19-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites “a filter line interposed between the first and second valves and communicating with a filter medium”. It is not clear, what is meant by “a filter line ... communicating with a filter medium”. If the filter line does not comprise the filter medium, then it is not clear, why it is called the “filter line”. Moreover, the specification unambiguously discloses: “a filter medium is disposed **in** the filter line” (page 3).

Claim 20 recites “a needle” as a sampling means. It is not clear, what type of a needle is meant here, as needles can be solid. If this is a syringe needle capable of holding liquid in its channel, this should be recited in the claim to eliminate indefiniteness of the claim recitation.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claims 19-20 and 25-36** are rejected under 35 U.S.C. 103(a) as being unpatentable over the Prior Art Disclosed by the Applicants (PADA) in view of Blake-Coleman et al. (US 4,848,139).

PADA discloses automated system for handling liquids represented in Figure 1. PADA does not disclose a filter assembly installed on Liquid Handling (LH) unit.

Blake-Coleman discloses a filter assembly, comprising a first valve 66, a second valve 64, and a filter line 60 with a filter medium 62 interposed between the valves, along with the by-pass line 58 (Figure 2) for handling fluids containing bacteria for comparative analysis of fluids comprising bacteria and purified from bacteria.

It would have been obvious for anyone of ordinary skill in the art to install Blake-Coleman's filter assembly in PADA's apparatus for comparative analysis of liquids containing undissolved material and pure solutions, because this allows implying PADA's apparatus for high-throughput comparative screening.

11. **Claims 21-23** are rejected under 35 U.S.C. 103(a) as being unpatentable over PADA in view of Blake-Coleman as applied to claims 19-20 and 25-36 above, and further in view of Messing (US 3,930,951).

PADA in view of Blake-Coleman do not specifically disclose ultrasonic bath.

Messing discloses using ultrasonic bath for dissolving a solid [4,4'-bi (2-methoxy-benzenediazonium chloride)] in water.

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It would have been obvious for anyone of ordinary skill in the art to use ultrasonic bath for preparing liquids from solids in PADA-Blake-Coleman's apparatus, because this expands the use of PADA-Blake-Coleman's liquid handling apparatus for solid samples by including dissolving solid samples.

12. **Claim 24** is rejected under 35 U.S.C. 103(a) as being unpatentable over PADA in view of Blake-Coleman and Messing, as applied to claims 21-23 above, and further in view of Dorsey (US 4,919,804).

While PADA in view of Blake-Coleman and Messing do not disclose regulating the ultrasonic bath using a cooling tube for transferring heat, Dorsey discloses, "temperature control of the ultrasonic bath was accomplished by passing a thermostatted solution of ethylene glycol and water through coiled copper tubing lining the inner perimeter of the bath" (col. 4, lines 3-7).

It would have been obvious for any routineer in the art to use Dorsey's thermostatic system for ultrasonic bath in PADA-Blake-Coleman-Messing's apparatus, because it is a simple and convenient system to be implemented in the automated liquid handling apparatus.

13. **Claims 19-20 and 25-36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenyon et al. (WO 93/07311) in view of the Standard Protocol for Screening Solid (SPSS) disclosed by the Applicants (page 2) and Blake-Coleman.

Kenyon discloses a fully automated system for crystallizing a plurality of compounds depicted on Figures 8 and 9, which corresponds to the automated system recited in the pending claims, except for a filtering assembly and ultrasonic bath for dissolving solids.

SPSS, according to the Applicants discloses: "the protocol for screening crystal forms may generally involve: (1) dissolving the drug in a solvent medium, (2) evaporating solvent, cooling the drug/solvent mixture, or adding an antisolvent to increase the degree of supersaturation of the drug in the solvent medium and (3) characterizing the resulting products using techniques such as polarized light microscopy, thermal analysis, Raman spectroscopy, and X-ray powder diffraction" (p. 2).

It would have been obvious for anyone of ordinary skill in the art to modify Kenyon's apparatus by including means for dissolving solids and filtering resultant solutions before crystallizing, because SPSS discloses these steps as conventional for screening crystal forms, and

Kenyon's apparatus is applied for screening crystal forms of drugs, with the latter usually present as solid formulations.

It would have been obvious to use Blake-Coleman's filter assembly for Kenyon's apparatus, because it is a simple assembly for implication in the automated system.

14. **Claims 21-23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenyon in view of SPSS and Blake-Coleman, as applied to claims 19-20 and 25-36 above, and further in view of Messing (US 3,930,951).

Kenyon in view of SPSS and Blake-Coleman do not specifically disclose ultrasonic bath.

Messing discloses using ultrasonic bath for dissolving a solid [4,4'-bi (2-methoxy-benzenediazonium chloride)] in water.

It would have been obvious for anyone of ordinary skill in the art to use ultrasonic bath for preparing liquids from solids in Kenyon-SPSS-Blake-Coleman's apparatus, because this expands the use of Kenyon-SPSS-Blake-Coleman's liquid handling apparatus for solid samples by including dissolving solid samples.

15. **Claim 24** is rejected under 35 U.S.C. 103(a) as being unpatentable over Kenyon in view of SPSS, Blake-Coleman and Messing, as applied to claims 21-23 above, and further in view of Dorsey.

While Kenyon in view of SPSS, Blake-Coleman and Messing do not disclose regulating the ultrasonic bath using a cooling tube for transferring heat, Dorsey discloses "temperature control of the ultrasonic bath was accomplished by passing a thermostatted solution of ethylene glycol and water through coiled copper tubing lining the inner perimeter of the bath" (col. 4, lines 3-7).

It would have been obvious for any routineer in the art to use Dorsey's thermostatic system for ultrasonic bath in Kenyon-SPSS-Blake-Coleman-Messing's apparatus, because it is a simple and convenient system to be implemented in the automated liquid handling apparatus.

In general, it would have been obvious to automate all substructures of such automated system, because *In re Venner*, 120 USPQ 192 (CCPA 1958): "to provide a mechanical or automatic means to replace manual activity which accomplishes the same result is within the skill of a routineer in the art".

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. *Midler (US 3,892,539)* teaches "process for production of crystals in fluidized bed crystallizers" (Title), the system provided "with a by-pass line 111 connecting pipe 87 with holding tank 99, this by-pass line containing a valve 112. When such a by-pass line is provided, there is also provided in line 87, between by-pass line 111 and the dissolver tank 80, a valve 113. During the normal operation of the system, valve 113 is open and valve 112 is closed, so that the by-pass line 111 is ineffective. However, when it is desired to suspend the normal operation of the system, as for example at nights and weekends when no one is present to feed crude solids to the dissolver tank 80 and to supervise the operation of the system, valve 113 is closed and valve 112 is opened". *Johnson (US 5,240,467)* teaches "multistage countercurrent recrystallization process and apparatus for performing same" (Title), comprising "a multistage process for the separation and purification of a desired crystalline material by repeated dissolution and recrystallization, wherein crystals and solvent move countercurrent to one another through the stages" (Abstract), utilizing filtration of the solution through filters 52.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yelena G. Gakh

9/22/04

Handwritten signature of Yelena G. Gakh in cursive script.